

Substitute for form 1449A/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;"><i>(Use as many sheets as necessary)</i></p>				<b>Complete if Known</b>	
				Application Number	10/579,251
				Filing Date	October 20, 2006
				First Named Inventor	Luca Gianni
				Art Unit	1623
				Examiner Name	Jonathan S. Lau
				Attorney Docket Number	13566.105020
Sheet	1	of	2		

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		20020173482	11-21-2002	Jafferhusen Abdulhusen Ajani	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 02/078678	10-10-2002	Shire Biochem Inc.		
		WO 03/020259	03-13-2003	Cancer Research Technology Limited		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Sheet 2 of 2	Attorney Docket Number	13566.105020	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Committee on Risk Assessment Methodology, "Issues in Risk Assessment. Appendix A: Workshop Summary- Maximum Tolerated Dose: Implications for Risk Assessment," National Research Council, National Academy of Sciences, National Academies Press, Washington DC, pp. 79-89, 1993	
		Donald et al, "Comparison of four modulators of drug metabolism as protectants against the hepatotoxicity of the novel antitumor drug yondelis (ET-743) in the female rat and in hepatocytes in vitro," Cancer Chemother Pharmacol, April 2004, vol. 53, pp. 305-12	
		Hussein et al., "A Phase II Trial of Pegylated Liposomal Doxorubicin, Vincristine, and Reduced-Dose Dexamethasone Combination Therapy in Newly Diagnosed Multiple Myeloma Patients," Cancer, November 15, 2002, vol. 95, No. 10, pp. 2160-2168	
		Newell et al., "The Cancer Research UK experience of pre-clinical toxicology studies to support early clinical trials with novel cancer therapies," European Journal of Cancer, v. 40, pp. 899-906, 2004	
		FDA Draft Guidance, "Nonclinical Evaluation for Anticancer Pharmaceuticals," downloaded from the internet October 2, 2009, << <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm085389.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm085389.pdf</a> >>	

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